



Serial No.: 09/857,795  
Inventor/s: NOMURA et al.

C#/M#: 159-67  
Atty: Arthur R. Crawford  
Date: July 19, 2001

Title: MEDICINAL COMPOSITIONS FOR ORAL USE

Amendment  
Pages Specification, Claims & Abstract  
Claims

xx  
xx

Sheets of Drawings  
Declaration (1 Pages)  
Assignment (1 Pages) Including Cover  
Priority Document(s)  
Base Issue Fee Transmittal

\$40.00 Fee (Check) - Pre-Bill

\$ Fee (Check) - Non Pre-Bill

**\$40.00 = Total Fee Enclosed**

Other:



FORM PTO-1390 (REV 11-2000)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER <b>159-67</b>
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)  <b>09/857,795</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP00/07045</b>	INTERNATIONAL FILING DATE <b>11 October 2000</b>	PRIORITY DATE CLAIMED <b>12 October 1999</b>

TITLE OF INVENTION

**MEDICINAL COMPOSITIONS FOR ORAL USE**

APPLICANT(S) FOR DO/EO/US

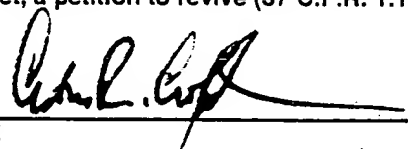
**NOMURA et al.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The U.S. has been elected by the expiration of 19 months from the priority date (Article 31).
5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has **NOT** expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 To 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information.

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) <b>09/857,795</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP00/07045</b>		ATTORNEY'S DOCKET NUMBER <b>159-67</b>	
21. <input checked="" type="checkbox"/> The following fees are submitted:				<b>CALCULATIONS</b> PTO USE ONLY	
<b>BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5):</b> -- N either international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.....\$1000.00 -- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO.....\$860.00 -- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO.....\$710.00 -- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4).....\$690.00 -- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4).....\$100.00					
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				\$	0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).				\$	0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20	-20 =	0	X	\$18.00
Independent Claims	3	-3 =	0	X	\$80.00
MULTIPLE DEPENDENT CLAIMS(S) (if applicable)					\$270.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.					0.00
<b>SUBTOTAL =</b>				\$	0.00
Processing fee of \$130.00, for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)).					0.00
<b>TOTAL NATIONAL FEE =</b>				\$	0.00
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property				+	\$ 40.00
a for Petition to Revive Unintentionally Abandoned Application (\$1240.00 - Small Entity = \$620.00)				+	\$ 0.00
<b>TOTAL FEES ENCLOSED =</b>				\$	40.00
				Amount to be:	
				refunded	\$
				Charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$40.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 14-1140 in the amount of \$_____ to cover the above fees. A duplicate copy of this form is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed. d. <input checked="" type="checkbox"/> The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.					
<b>NOTE:</b> Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
<b>SEND ALL CORRESPONDENCE TO:</b>  NIXON & VANDERHYE P.C. 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000					
				 SIGNATURE	
				<b>Arthur R. Crawford</b> NAME	
				<b>25,327</b> <b>July 19, 2001</b> REGISTRATION NUMBER      Date	

RECORDATION FORM COVER SHEET

PATENTS ONLY

Our Ref.: 159-67

Commissioner of Patents and Trademarks  
Box Assignment, Washington, D.C. 20231

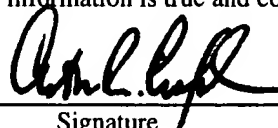
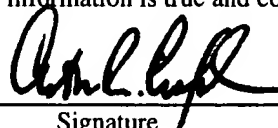
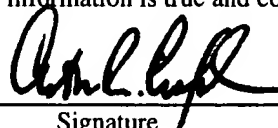
To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

<p>1. Name of conveying party(ies): Masaaki NOMURA Takumi KOJIMA Shigenori NOZAWA</p> <p>Additional name/s of conveying party/ies attached? <input type="checkbox"/></p> <p>3. Nature of conveyance: <input checked="" type="checkbox"/> Assignment <input type="checkbox"/> Merger <input type="checkbox"/> Security Assignment <input type="checkbox"/> Change of Name <input type="checkbox"/> Other _____</p> <p>Execution Date: _____ July 2, 2001</p>	<p>2. Name and address of receiving party(ies):</p> <p>Name: <u>SUNTORY LIMITED</u> Internal Address: _____ Street Address: <u>1-40, Dojimahama 2-chome, Kita-ku,</u> <u>Osaka-shi</u> _____ City: <u>Osaka</u> State/Country: <u>Japan</u> Zip: <u>530-8203</u></p> <p>Additional name/s &amp; address/es attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
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<p>4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the application is: _____</p> <table border="0"><tr><td style="vertical-align: top;"><p>A. Patent Application No(s). (1) <u>09/857,795</u> (2) _____ (3) _____</p></td><td style="vertical-align: top;"><p>B. Patent No(s). (1) _____ (2) _____ (3) _____</p></td></tr></table> <p style="text-align: center;">Additional numbers attached <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>		<p>A. Patent Application No(s). (1) <u>09/857,795</u> (2) _____ (3) _____</p>	<p>B. Patent No(s). (1) _____ (2) _____ (3) _____</p>
<p>A. Patent Application No(s). (1) <u>09/857,795</u> (2) _____ (3) _____</p>	<p>B. Patent No(s). (1) _____ (2) _____ (3) _____</p>		

<p>5. Name and address of party to whom correspondence concerning document should be mailed:</p> <p>Name: _____ Arthur R. Crawford</p> <p>Internal Address: _____</p> <p>Street Address: <u>Nixon &amp; Vanderhye P.C.</u> <u>1100 North Glebe Road</u> <u>8<sup>th</sup> Floor</u> City: <u>Arlington</u> State: <u>VA</u> Zip: <u>22201</u></p>	<p>6. Total number of applications &amp; patents involved: <u>1</u></p> <p>7. Total fee (37 CFR 3.41) \$ <u>40.00</u> <input checked="" type="checkbox"/> Enclosed <input type="checkbox"/> Authorized to be charged to deposit account #14-1140</p> <p>8. The Commissioner is hereby authorized to charge any deficiency in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper thereafter filed in this application by this firm) to our Account N . 14-1140.</p>
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DO NOT USE THIS SPACE

<p>9. Statements and signature. To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.</p> <table border="0" style="width: 100%;"><tr><td style="text-align: center; width: 33%;"><p>_____ Name of Person Signing Reg. No. 25,327</p></td><td style="text-align: center; width: 33%;"><p> Signature</p></td><td style="text-align: center; width: 33%;"><p>_____ Date</p></td></tr></table> <p style="text-align: right;">July 19, 2001</p> <p style="text-align: right;">Total number of pages including original cover sheet, attachments, and document: [2]</p>			<p>_____ Name of Person Signing Reg. No. 25,327</p>	<p> Signature</p>	<p>_____ Date</p>
<p>_____ Name of Person Signing Reg. No. 25,327</p>	<p> Signature</p>	<p>_____ Date</p>			

07/24/2001 MNGUYEN 00000054 09857795

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UNITED STATES PATENT AND TRADEMARK OFFICE

OLT/MATTER # 159

MAIL DATE 7/26/01

DUE DATE Sept 26, 2001

FINAL DEADLINE 10/26/2001

DOCKETED BY MR/0165

Commissioner of Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NO.

09/857795

FIRST NAMED APPLICANT

NOMURA

M

ATTY. CORRESP. NO.

159-67

INTERNATIONAL APPLICATION NO.

PCT/JP00/07045

NIXON & VANDERHYE  
1100 NORTH GLEBE ROAD 8TH FLOOR  
ARLINGTON, VA 22201 4714

I.A. FILING DATE

11 OCT 00

PRIORITY DATE

12 OCT 99

26 JUL 2001

DATE MAILED:

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☒ a Designated Office (37 CFR 1.494) ☐ an Elected Office (37 CFR 1.495):

- ☒ U.S. Basic National Fee. ☐ Indication of Small Entity Status.  
☒ Copy of the international application. ☒ Translation of the international application into English.  
☐ Oath or Declaration of inventors(s). ☐ Translation of Article 19 amendments into English.  
☐ Copy of Article 19 amendments. ☐ Other:  
☒ Priority Document.  
☐ The International Preliminary Examination Report in English and its Annexes, if any.  
☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☒ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee. ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.  
☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).  
☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.  
☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$\_\_\_\_\_ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.  
 7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

***A copy of this notice MUST be returned with this response.***

Enclosed: ☐ PCT/DO/EO/917☐ Notice of Defective Translation☐ PTO-875☐ PCT/DO/EO/920

Karen Williams

*KW*

FORM PCT/DO/EO/905 (March 2001)

Telephone: 703-305-3688